IMPROVED PACKAGE WITH ELECTRONIC CIRCUITRY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to co-pending U.S. Provisional Application No. 60/477,514, filed on June 10, 2003, which is entirely incorporated herein by reference.

FIELD OF THE INVENTION

The present invention relates generally to systems and methods used for monitoring the dispensing, accessing, delivering or using of packaged items. More specifically the present invention is directed to monitoring healthcare behavior, such as compliance with a medication regimen. Accordingly, the embodiments described are improved pharmaceutical packages and pharmaceutical package inserts that include electronic circuitry for use with an electronic monitoring device.

BACKGROUND OF THE INVENTION

It is known to provide systems and methods for tracking the usage and delivery of medications. Mechanical dispensing systems are known and, more recently, pharmaceutical packages with various electronic monitoring features have been developed.

With regard to pharmaceutical packages that incorporate electronic monitoring features, it is known to construct an apparatus for dispensing medications from a uniquely shaped single foldable sheet that includes an internal electronic circuit. Further, it is known to construct a multi-layer protective seal which likewise includes an internal electronic circuit. Although the known devices create unique packages and provide certain features, they do not provide solutions that can be cost-effectively integrated into standard manufacturing processes or used together with existing package configurations.

Accordingly, there remains in the art a need for a system and method for electronically monitoring the dispensing of packages items, particularly medications in pharmaceutical packages, that is easily adapted for use with standard manufacturing processes and/or existing package configurations.

SUMMARY OF THE INVENTION

The present invention overcomes the deficiencies of the known art and the problems that remain unsolved by providing insertable cards which can be used together to form a package with electronic circuitry, or are easily integrated into existing manufacturing processes and package configurations to provide electronic monitoring functionality.

One component of an illustrated embodiment is a fold-over card. This fold-over card includes an array of open cells. Another component of an illustrated embodiment is a blister card. This blister card includes an array of receptacles with open sides for receiving items. A third component of an illustrated embodiment is a backing card that includes an array of breachable closed cells. After the items are deposited into the receptacles, the backing card is attached to the fold-over card in a manner that captures the items and seals the open side of the receptacles. A subsequent component of this embodiment is a trace card comprising an array of breachable closed cells and circuitry that spans these closed cells. Here the circuitry is printed on the trace card using conductive inks and conventional printing methods.

In assembling the above-referenced cards, the closed cells of the trace card are aligned with the closed cells of the backing card (or the receptacles, in the absence of a closed cell backing card), to facilitate access to the items. To access the items the user eventually breaches the circuit associated with the selected items and related closed cell. Upon exerting sufficient

force on the item from a pliable end of the receptacle the item is pushed through the first closed cell, whether the first closed cell is located on the fold-over card or backing card. The user continues to push the item until it breaches the circuit spanning the related closed cell of the trace card. Upon breaching the cell bridge and related closed cell, the related closed circuit is broken. The breaking of the circuit is received and stored by an electronic monitoring device as the event of accessing the item.

Additional embodiments are contemplated and taught herein. One embodiment comprises a combined fold-over and blister card, together with a backing card and a trace card. Another embodiment comprises a combined blister and backing card, together with a trace card. Yet another embodiment comprises a fold-over card, a blister card, a foil backing, and a trace card with a dielectric overlay. In practice these additional embodiments may be constructed and used as described above.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is an exploded view of an embodiment of the present invention.

FIG. 2 is an exploded view of an embodiment of the present invention.

FIG. 3 is a plan view of the circuitry of FIG. 1 and FIG. 2.

DETAILED DESCRIPTION OF THE INVENTION

Generally speaking the systems and methods described herein are directed to electronically monitoring the removal of an item from a defined location, such as an enclosed package. By applying what is taught herein to existing package configurations or package assembly methods, it is easy to monitor the dispensing, accessing, delivering or using of a packaged item.

As required, embodiments of the present invention are disclosed herein; however, it is to be understood that the disclosed embodiments are merely exemplary of the invention that may be embodied in various and alternative forms. The figures are not necessarily to scale and some features may be exaggerated or minimized to show details of particular components. Therefore, specific structural and functional details disclosed herein are not to be interpreted as limiting, but merely as a basis for the claims and as a representative basis for teaching one skilled in the art to variously employ the present invention. For purposes of teaching and not limitation, the illustrated embodiments are directed to pharmaceutical packages.

Referring now to the drawings wherein like elements are represented by like numerals, FIG. 1 illustrates an exploded view of an exemplary Improved Package with Electronic Circuitry ("PEC") **10**, configured for use with the dispensing of medications in tablet form.

One component of this PEC **10** is a punched fold-over card **20**. Typically a fold-over card is constructed of inexpensive disposable sheet-like material such as paper, paperboard, cardboard, plastic, or any combination thereof. This fold-over card **20** includes an array of open cells **22**, formed by a prior pre-assembly step, such as a cutting, punching, scoring or forming depending on the material used. The illustrated fold-over card **20** further includes score lines **24** to facilitate final assembly as described below, and a locking tab **26** to be used as described below.

Another component of this PEC **10** is a blister card **28**. This blister card **28** includes an array of blister cells **29**. Typically a blister card **28** is thermo-formed from a plastic-type material to create blister cells **29**, pliable protruding (concave when viewed from side A of the blister card) receptacles for receiving and storing medication in tablet form (not shown) to be

accessed by a user. The actual configuration of the blister cards **28** and materials used are merely design choices.

Following an exemplary assembly process of a pharmaceutical manufacturer, side B of the blister card **28** is receivingly mated to side C of the fold-over card **20** so that each blister cell **29** is aligned with and nested within a respective open cell **22**. In this configuration the blister cells **29** are ready to receive the medication tablets. Of course, side A of the blister card **28** may be mated with side D of the fold-over card **20** so that each blister cell **29** is aligned with a respective open cell **22** and ready to receive the medication tablets. The order of assembling these two cards **20, 28** does not determine when the medication tablets are deposited into the blister cavities **29**. Accordingly the manufacturer does not need to alter its assembly process with regard to the components and steps described so far.

Another component of this PEC **10** is a backing card **30**. This backing card **30** includes an array of closed cells **32**, which are best described as locations designed to facilitate breaching a card by pushing through a perforated or scored cell gate. Here the backing card **30** is constructed of non-conductive material. After the medication tablets are deposited into the blister cells **29**, the backing card **30** is attached to the fold-over card **28** in a manner that captures the tablets and seals the blister cells **29**. The backing card **30** may perform any or all additional functions, including receiving graphics, structural support, and insulting against the electronics described below. In the embodiment illustrated the backing card **30** is attached to side A of the blister card **28** and/or side C of the fold-over card **20**. And for the reasons explained below, each closed cell **32** is aligned with a respective blister cavity **22**.

It may be because of design criteria or the nature of the items being monitored that the fold-over card **20** and backing card **30** may be combined to perform the same functions. For

example, in the illustrated embodiment the open cells **22** may be replaced with closed cells **32** and side A of the blister card **28** may be attached directly to side D of the fold-over card **20** after the tablets are deposited into the blister cells **29**. Alternatively the blister card **28** may be configured to resemble the fold-over card **20** and attached directly to the backing card **30**, after the tablets are deposited into the blister cells **29**, such that each blister cell **29** is aligned with a respective closed cell **32**.

A subsequent component of this PEC **10** is a trace card **40** comprising an array of closed cells **32** and circuitry **42**. Here the trace card **40** is constructed of non-conductive material such as but not limited to paper, paperboard, cardboard, plastic, or any combination thereof. Here also, by way of illustration and not limitation, the configuration of the trace card **40** mimics the configuration of the fold-over card **20** and backing card **30**. It is contemplated that the configuration of the trace card **40** is merely a design choice selected to best fit with new or existing packages or package manufacturing processes.

The illustrated circuitry **42** is applied directly on the trace card **40**, in a manner well known by those skilled in the art. Here the circuitry **42** is printed on the trace card **40** using conventional printing or lithography methods such as but not limited to screen or off-set methods. The inks used in the printing method to form the circuitry **42** are conductive inks, selected based on the performance needs of the individual circuits **44**. Conductive inks typically include conductive metals such as but not limited to copper or silver. Here the ink used to form the illustrated circuitry **42** is a carbon-based conductive ink readily understood by those skilled in the art.

As best illustrated in FIG. 3, the configuration of the circuitry **42** is likewise a design choice which, in a preferred embodiment, is based at least in part on the positions of the cells **29**,

32. As is shown in FIG. 3 and will be understood by those skilled in the art, each individual closed circuit **44** typically extends from and returns to an electronic monitoring device (EMD, not shown) located at an electronic monitoring receiving area **46**, and bridges a closed cell **32**. In practice, when a closed cell **32** of the trace card **40** is opened as described below, the respective circuit **44** is broken. Here the breaking of a circuit **44** signals the removal of a tablet, an event that is captured and recorded by the EMD. Individual circuits **44** may be as wide or as narrow as required by the voltage and resistance requirements of the embodiment in use, but in the illustrated embodiments it is shown to widen the circuitry **42** over cells **32** and score lines **24** to reduce or eliminate false readings. Accordingly, the circuitry **42** comprises cell bridges **48** and score line bridges **50**. It is contemplated that individual circuits **44** may be configured to accommodate switches, controls, and similar components that enhance monitoring functions.

In assembling the PEC **10** illustrated herein, the closed cells **32** of the trace card **40** are aligned with the closed cells **32** of the backing card **30** (or the blister cells **29**, in the absence of a closed cell backing card), to facilitate access to the tablets. To access the tablet the user eventually breaches the cell bridge **48** associated with the selected tablet. Upon exerting sufficient force on the tablet from the outside surface of the blister cell **29** the tablet is pushed through the first closed cell **32**, whether the first closed cell **32** is located on the fold-over card **20** or backing card **30**. The user continues to push the tablet until it breaches the cell bridge **48** spanning the related closed cell **32** of the trace card **40**.

Upon breaching the cell bridge **48** and related closed cell **32**, the related closed circuit **44** is broken. The breaking of the circuit **44** is received and stored by the EMD as the event of accessing the tablet. Indicia regarding that event, including time of day, date, sequence or any number of event labeling indicia, as programmed in the EMD or devices in communication with

EMD, may also be recorded and stored by the EMD. This event related indicia stored by the EMD may be read, retrieved, or transmitted as provided by the EMD in a manner understood by those skilled in the art.

The embodiment illustrated in FIG. 1 is described as being constructed of materials and by methods common to the industry example provided. The advantages of constructing embodiments with inexpensive materials and by manufacturing methods commonly used are readily apparent and do not require further explanation. Likewise, producing a system with a look and feel readily familiar to most consumers provides known advantages. Accordingly the use of insertable cards **20, 30, 40** to provide the flexibility to an existing industry application or existing package configuration is another advantage of the present invention.

For example, after assembly the PEC **10** may be combined with the outer sleeve taught in U.S. Patent 6,047,829 (the '829 patent), assigned to the present applicant and incorporated herein by reference, by folding and inserting the PEC **10** into the outer sleeve as taught by the '829 patent. Alternatively trace card **40** of any by itself but complete with circuitry **42** and an EMD, may be attached to or combined with the inner slide card taught by the '829 patent. Thereafter, the unit dose packaging system taught therein, like any package configuration that includes an embodiment of the trace card **40**, is enabled to electronically monitor the dispensing, accessing, delivering or using of the packaged items.

With regard to FIG. 2, in the healthcare industry it is known to use foil guard technology to seal and protect pharmaceuticals delivered in blister cards **28**. Applying the teachings of the present invention to the embodiment PEC **60** there is shown a blister card **28** with tablets (not shown) configured to receive a protective film of foil **62** in a manner well known by those skilled

in the art, that is, so that the foil **62** seals the blister cells **29** by being positioned immediately adjacent to side A of the blister card **28** and/or side C of the fold-over card **20**.

Integrating the trace card **40** into the known foil guard technology requires only minor enhancement to the circuitry **42**. It is known that foil **62** is conductive and the circuitry **42** is conductive. To eliminate electrical interference between the foil **62** and circuitry **42** with minimal impact on the present standard foil guard manufacturing process, a dielectric circuit overlay **64** is provided. In the illustrated embodiment the dielectric circuit overlay **64** is a non-conductive ink printed directly over the conductive printed circuitry **42** using the printing processes referenced herein. It will be understood that the overlay **64** may exactly follow and cover each circuit **44** and components **48, 50**, or more broadly cover the circuit side of the trace card **40** where non-conductivity between the circuitry **42** and foil **62** is desired. It will be further understood that the overlay **64** may be any non-conductive thin covering, whether inks or plastics convenient to the manufacturer, that provides a sufficient dielectric barrier between the foil **62** and circuitry **42**.

By adding the trace card **40** with its circuitry **42** and dielectric circuit overlay **64** to the standard foil guard technology manufacturing process, possibly as a last step or an outsourced step, the pharmaceutical manufacturer can add monitoring and compliance functions with minimum impact to its existing processes.

The embodiments taught herein are directed to single-use disposable packing, however such embodiments are not a limitation as reusable packing is contemplated. For example the blister cells **29** illustrated may be constructed of a durable latex and the backing card **30** illustrated may be constructed of a rigid metal or plastic with closed cells **32** that permit repeated access, such as are available with a hinged or replaceable friction-fit cell gate.

It will emphasized that the above-described embodiments of the present invention are merely possible examples of implementations set forth for a clear understanding of the principles of the invention. Many variations and modifications may be made to the above-described embodiments of the invention without departing substantially from the spirit and principles of the invention. All such modifications and variations are intended to be included herein within the scope of this disclosure and the present invention and protected by the following claims.